



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,396	03/31/2004	Benjamin D. McDaniel	51992/AW/W112	9596

23363 7590 10/17/2005  
CHRISTIE, PARKER & HALE, LLP  
PO BOX 7068  
PASADENA, CA 91109-7068

EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/816,396	<b>Applicant(s)</b> MCDANIEL ET AL.	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6, 10, 16 and 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 11-15 and 17-22 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/14/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, the embodiment of the catheter shown in Figs. 1-8.

Species II, the embodiment of the catheter with a self-expanding framework shown in Figs. 9-10.

Species III, the embodiment of the catheter with longitudinal slots shown in Figs. 11-14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are held to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 3739

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Through a telephone conversation with Anne Wang on September 28, 2005 and a subsequent voicemail message received on October 3, 2005, a provisional election was made without traverse to prosecute the invention of Species I shown in Figs. 1-8, claims 1-5, 7-9, 11-15, and 17-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6, 10, 16, and 23-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Objections***

Claim 13 is objected to because of the following informalities: Line 3 should read "having proximal and distal ends," not "having proximal end distal ends." Line 5 should read "and a distal end," not "an a distal end." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim specifies an expander attached at or near its distal end to proximal ends of the tensile members. On page 11, lines 2-3, the specification, however, states that the tensile members are attached "to the expander 26 at their distal ends, and to the catheter body 12 at their proximal ends." Therefore, the specification does not enable the attachment of the tensile members at their proximal ends to the expander.

In the paragraph starting at the bottom of page 2 and continuing to the top of page 3, the specification further maintains that the spines of U.S. Application 10/017564 are connected at their proximal and distal ends to the expander (Fig. 5 of 10/017564 and similarly Fig. 7 of 10/816396, the application examined herein). In both figures, however, the spines do not appear to be attached to the expander as claimed by applicant. Rather, they appear to be indirectly in contact with each other inside the catheter. For the purposes of examination, the Office interprets connection to the expander as defined by Fig. 7 in the preceding description.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3739

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 13, 17-20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Diederich et al. (U.S. Pat. No. 6,117,101).

Regarding claim 1, Diederich et al. disclose a catheter comprising:

an elongated catheter body 652 having proximal and distal ends and at least one lumen therethrough (Fig. 13);

a three-dimensional ablation assembly 650 at or near the distal end of the catheter body, said assembly having a framework 651 defining a length and a circumference, the assembly movable into a collapsed configuration with a greater length and a lesser circumference and an expanded configuration with a lesser length and a greater circumference, the framework comprising a plurality of tensile members interwoven in a manner such that the length increases as the circumference decreases and vice versa (col. 26, ln. 38-44 and Fig. 13);

said assembly also having a ribbon electrode extending along said circumference, said ribbon electrode adapted to move with said framework (col. 27, ln. 12-25).

Regarding claim 2, Diederich et al. disclose the catheter of claim 1, wherein said framework of the assembly in the expanded configuration has a first circumference in a first section along its length and a different second circumference in a second section along its length (col. 26, ln. 38-44 and Fig. 13).

Regarding claim 3, Diederich et al. disclose the catheter of claim 1, further comprising an expander 653 attached at or near its distal end to distal ends of the tensile members and extending through the catheter body (col. 26, ln. 26-35), the expander having a proximal end that extends out the proximal end of the catheter, and having a lumen extending therethrough, whereby, in use, the expander can be moved longitudinally relative to the catheter body to expand and collapse the assembly (col. 26, ln. 34-44 and Fig. 13). Since the expander 653 is used to expand the ablation assembly, it must inherently have a proximal end that extends out the proximal end of the catheter body so that the user can actuate it.

Regarding claim 4, Diederich et al. disclose the catheter of claim 1, further comprising an expander 653 attached at or near its distal end to distal ends of the tensile members 651 and extending through at least a distal portion of the catheter body 652, whereby, in use, the expander can be moved longitudinally relative to the catheter body to expand and collapse the assembly (col. 26, ln. 26-44 and Fig. 13)

Regarding claim 7, Diederich et al. disclose the catheter of claim 1, wherein the expander is moved proximally to actuate the assembly into the expanded configuration (Fig. 13).

Regarding claim 13, Diederich et al. disclose the catheter of claims 1 and 3, wherein the expander has a proximal end attached to a control handle. Since the expander is used to actuate the assembly expansion, the expander must inherently have a control handle to allow the user to actuate the expander.

Art Unit: 3739

Regarding claim 17, Diederich et al. disclose the catheter of claims 1 and 3, wherein the expander 653 is generally coaxial with the catheter body 652 (Fig. 13).

Regarding claim 18, Diederich et al. disclose the catheter of claims 1 and 3, wherein the expander 653 forms the axis of the assembly 650 (Fig. 13).

Regarding claim 19, Diederich et al. disclose the catheter of claim 1, wherein the assembly 650 comprises at least four tensile members 651 (Fig. 13).

Regarding claim 20, Diederich et al. disclose the catheter of claim 1, wherein each tensile member 651 comprises an internal flexible wire and a non-conductive covering over the flexible wire (col. 27, ln. 5-6 and Fig. 13).

Regarding claim 22, Diederich et al. disclose the catheter of claim 1, wherein the ribbon electrode is elastic (col. 27, ln. 12-25).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.



Art Unit: 3739

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 8-9, 11-12, 14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. ('101) in view of Webster, Jr. (U.S. Pat. No. 5,772,590).

Regarding claim 5, Diederich et al. disclose the catheter of claim 1, further comprising an expander 653 attached at or near its distal end to distal ends of the tensile members 651 and extending through at least a distal portion of the catheter body 652, whereby, in use, the expander can be moved longitudinally relative to the catheter body to expand and collapse the assembly (col. 26, ln. 26-44 and Fig. 13). The claim differs in calling for the expander to be attached at or near its distal end to proximal ends of the tensile members.

Webster, Jr., however, teaches an expandable electrode catheter with an expander 54 attached at or near its distal end to proximal ends of the tensile members 52 to allow the expander to expand the tensile members when moved longitudinally in a proximal direction (Figs. 9-11). This attachment of Webster, Jr. is clearly analogous to the attachment shown in Fig. 7 of the application.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the expander of Diederich et al. attached at or near its distal end to proximal ends of the tensile members in view of the teaching of Webster, Jr. to allow the expander to expand the tensile members when moved longitudinally in a proximal direction.

Art Unit: 3739

Regarding claim 8, Diederich et al. disclose the catheter of claim 1. Diederich et al. also disclose the catheter of claim 5 in view of Webster, Jr. In addition, Diederich et al. disclose a catheter 652, wherein the distal portion of the catheter partially covers the proximal portion of the assembly (Fig. 13). The claim differs from Diederich et al. in calling for the expander to be moved proximally to withdraw the assembly into a distal portion of the catheter body. Webster, Jr., however teaches an expandable electrode catheter, wherein the expander is moved proximally to withdraw the assembly into a distal portion of the catheter body to allow the outer catheter 8 to protect the assembly while it is carried to and from the point of ablation (col. 4, ln. 47-67 and Figs. 8-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the expander of Diederich et al. move proximally to withdraw the assembly into a distal portion of the catheter body to protect the assembly while it is carried to and from the point of ablation.

Regarding claim 9, Diederich et al. disclose the catheter of claim 1. Diederich et al. also disclose the catheter of claims 5 and 8 in view of Webster, Jr. The claim differs from Diederich et al. in calling for the assembly to assume the collapsed configuration while withdrawn in the distal portion of the catheter body. Webster, Jr., however teaches an expandable electrode catheter, wherein the assembly assumes the collapsed configuration while withdrawn in the distal portion of the catheter body to allow the assembly to fit inside (col. 4, ln. 58-65 and Figs. 8-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the assembly of Diederich et al. assume the collapsed configuration while withdrawn in the

Art Unit: 3739

distal portion of the catheter body in view of the teaching of Webster, Jr. to allow the assembly to fit inside.

Regarding claim 11, Diederich et al. disclose the catheter of claims 1 and 3, wherein the expander comprises a tube (col. 26, ln. 34-36). The claim differs from Diederich et al. in calling for the expander to comprise plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with an expander 56 comprising plastic tubing (col. 9, ln. 12-13 and Fig. 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise plastic tubing in view of the teaching of Webster, Jr. because plastic is an obvious alternate material for constructing tubes that is well-known in the art.

Regarding claim 12, Diederich et al. disclose the catheter of claims 1 and 3, wherein the expander comprises a tube (col. 26, ln. 34-36). The claim differs from Diederich et al. in calling for the expander to comprise braided plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with tube 7 comprising braided plastic tubing (col. 5, ln. 13-16 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise braided plastic tubing in view of the teaching of Webster, Jr. because braided plastic is an obvious alternate material for constructing tubes that is generally known in the art (pg. 14 of applicant's specification).

Regarding claim 14, Diederich et al. disclose the catheter of claims 1, 3, and 13. The claim differs from Diederich et al. in calling for the control handle to comprise:

a handle housing having proximal and distal ends, and a piston having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body;

wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal movement of the expander relative to the catheter body to thereby expand and collapse the assembly.

Webster, Jr. ('590), however, teaches an expandable electrode catheter with a control handle 50 (Fig. 9) comprising the handle of U.S. Pat. No. 4,960,134 also to Webster, Jr. (incorporated by reference into Webster, Jr. '590).

With reference to Webster, Jr. ('134), the control handle 13 comprises:

a handle housing 40 having proximal and distal ends, and a piston 46 having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body 11 (col. 4, ln. 45-49 and Fig. 4);

With reference to Webster, Jr. ('590), the control handle 50 comprises an expander 54, wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal movement of the expander relative to the catheter body to thereby expand and collapse the assembly (col. 8, ln. 61 – col. 9, ln. 7 and Figs. 9-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the control handle of Diederich et al. to

Art Unit: 3739

comprise the control handle of Webster, Jr. ('590/'134) in view of Webster, Jr. ('590) as an obvious way to expand the tensile members of Diederich et al. that is known in the art.

Regarding claim 21, Diederich et al. disclose the catheter of claims 1 and 20. Diederich et al. further disclose that the internal flexible wire of each wire comprises a superelastic metal alloy, such as an alloy of nickel and titanium, or a combination of both (col. 26, ln. 63-65). The claim differs in calling for the internal flexible wire of each wire to comprise nitinol – a specific type of nickel and titanium alloy. Webster, Jr. ('590), however, teaches an expandable electrode catheter, wherein the tensile member wires comprise nitinol (col. 6, ln. 27-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the internal flexible wire of Diederich et al. from nitinol in view of the teaching of Webster, Jr. ('590) because nitinol is an obvious specific type of nickel and titanium alloy that is well-known in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Webster, Jr. ('590) in view of Edwards et al. (U.S. Pat. No. 5,471,982) and further in view of Webster, Jr. (U.S. Pat. No. 6,183,463 B1).

Regarding claim 15, Diederich et al. disclose the catheter of claims 1, 3, and 13. Diederich et al. also disclose the catheter of claim 14 in view of Webster, Jr. ('590). The claim differs from Diederich et al. in calling for the proximal end of the expander to extend outside the proximal end of the control handle and through a support tube.

Edwards et al. teach an expandable electrode catheter, wherein fluid is introduced to the point of ablation through the expander tube 240 to keep the electrodes free of tissue buildup and blood (col. 19, ln. 50 – col. 20, ln. 2 and Figs. 12 and 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included fluid introduction through the expander tube of Diederich et al. in view of the teaching of Edwards et al. to keep the electrodes free of tissue buildup and blood.

Webster, Jr. ('463) teaches an electrode catheter, comprising the piston control handle of Webster, Jr. ('590/'134) with a fluid introduction tube 88 that starts at the distal electrode end and then extends outside the proximal end of the control handle and through a support tube 91 (col. 8, ln. 18-26, col. 9, ln. 7-26, and Figs. 1-4). Fluid is introduced through the luer hub 90 (col. 8, ln. 33-39 and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the proximal end of the expander/fluid introduction tube of Diederich et al. in view of Edwards et al. to extend outside the proximal end of the control handle of Diederich et al. in view of Webster, Jr. ('590/'134) and through a support tube further in view of the teaching of Webster, Jr. ('463) as an obvious alternate way of introducing fluid that is known in the art for use with the control handle of Webster, Jr. ('590/'134).

Art Unit: 3739

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Pat. No. 4,699,147 to Chilson et al.  
U.S. Pat. No. 5,860,974 to Abele  
U.S. Pat. No. 6,826,420 B1 to Beatty et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT *AT*  
10/7/05

*Michael Peffley*  
MICHAEL PEFFLEY  
PRIMARY EXAMINER